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| 26294 7590 03/09/2010 TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVEVLAND, OH 44114 | | | | |
| EXAMINER | | | | |
| SGAGIAS, MAGDALINE K | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1632 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action
Before the Filing of an Appeal Brief

Application No.

10/565,616

Applicant(s)

UPTON ET AL.

Examiner

Magdalene K. Sgagias

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 February 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1,2,5,7,21-23 and 37.
Claim(s) withdrawn from consideration: 3-4, 6, 8-20, 24-28, 35-36.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632

Continuation of 3. NOTE: The amendment of claims 1, 22-23 and the newly added claim 38 require new search. Applicant's amendment to add the recitation in claim 1 (ii) and 23 "that does not comprise a heparin binding domain (HBD)" and the amendment to claim 22 to depend from the newly added claim 38 requires new search.

Continuation of 11. does NOT place the application in condition for allowance because: A. Applicants argue claims 1 and 23 have been amended to recite "vitronectin (VN) or an av integrin-receptor binding fragment thereof that does not comprise a heparin binding domain (HBD)." Applicants respectively submit that the amendments to claims 1 and 23 satisfy the requirements of 35 U.S.C. §112, first paragraph, because the present specification sufficiently describes the structure or functional nature of VN or an av integrin-receptor binding fragment thereof that does not comprise a HBD. For example, the present application discloses that the VN fragments may be characterized as: (i) having at least an av integrin-receptor binding region; and (ii) lacking a HBD (see p. 11, lines 3-25). With respect to the av integrin-receptor binding (or RGD) region of VN, this has been studied in numerous papers published prior to the priority date of the present invention. In fact, this domain has been mapped as far as the specific residues of VN that activate signaling pathways (see, e.g., Seger et al, J Biol Chem., 273(38):24805-24813, 1998; attached hereto). Additionally, the HBD of VN has been previously identified as the C-terminal region of mature VN (i.e., amino acid residues 347-459). The subject matter of amended claims 1 and 23 is also fully supported by the disclosure of International Application No. PCT/AU2004/000117 ("the '117 application"), which is incorporated by reference into the present application (see p. 11, line 9). For example, the '117 application discloses a number of different integrin-receptor binding VN fragments (see, e.g., p. 13, line 17 to p. 15, line 20). These arguments are not persuasive because they rely on the proposed amendments which have not been entered. Therefore, the rejection is maintained.

B. Applicants argue that new claim 38 satisfies the requirements of 35 U.S.C. §112, first paragraph, because one skilled in the art at the time of the present invention would have understood that the Applicants were in possession of an av integrin-receptor binding fragment comprising amino acid residues 1-52 of mature VN. Support for new claim 38 can be found at least p. 11, lines 15-25, and p. 13, line 28 to p. 14, line 1 of the present application. Additionally, one skilled in the art would appreciate that the claims recite VN fragments that are: (i) capable of binding to an av integrin-receptor (i.e., include at least an RGD) and (ii) lack the HBD. From this, the skilled artisan would understand that these features inevitably lead to a VN fragment that comprises amino acid residues 1-52 of mature VN.

These arguments are moot because applicants rely on the proposed amendment which has not been entered. Therefore, the rejection is maintained.